

UTILITY PATENT APPLICATION TRANSMITTAL

(Large Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No.
P-3576.07 CIPTotal Pages in this Submission
See postcard**TO THE ASSISTANT COMMISSIONER FOR PATENTS**Box Patent Application
Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

WORLD WIDE PATIENT LOCATION AND DATA TELEMETRY SYSTEM FOR IMPLANTABLE MEDICAL DEVICES

and invented by:

David L. Thompson

If a CONTINUATION APPLICATION, check appropriate box and supply the requisite information:

☐ Continuation ☐ Divisional ☒ Continuation-in-part (CIP) of prior application No.: 09/045,275

Which is a:

☒ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: 08/494,218

Which is a:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.:

Enclosed are:

Application Elements

1. ☒ Filing fee as calculated and transmitted as described below
2. ☒ Specification having 45 pages and including the following:
 - a. ☒ Descriptive Title of the Invention
 - b. ☒ Cross References to Related Applications (if applicable)
 - c. ☐ Statement Regarding Federally-sponsored Research/Development (if applicable)
 - d. ☐ Reference to Microfiche Appendix (if applicable)
 - e. ☒ Background of the Invention
 - f. ☒ Brief Summary of the Invention
 - g. ☒ Brief Description of the Drawings (if drawings filed)
 - h. ☒ Detailed Description
 - i. ☒ Claim(s) as Classified Below
 - j. ☒ Abstract of the Disclosure

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Application Elements (Continued)

3. ☒ Drawing(s) (when necessary as prescribed by 35 USC 113)
- a. ☐ Formal Number of Sheets _____
- b. ☒ Informal Number of Sheets 9
4. ☒ Oath or Declaration
- a. ☒ Newly executed (original or copy) ☐ Unexecuted
- b. ☐ Copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional application only)
- c. ☒ With Power of Attorney ☐ Without Power of Attorney
- d. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application,
see 37 C.F.R. 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation By Reference (usable if Box 4b is checked)
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
6. ☐ Computer Program in Microfiche (Appendix)
7. ☐ Nucleotide and/or Amino Acid Sequence Submission (if applicable, all must be included)
- a. ☐ Paper Copy
- b. ☐ Computer Readable Copy (identical to computer copy)
- c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

8. ☒ Assignment Papers (cover sheet & document(s))
9. ☐ 37 CFR 3.73(B) Statement (when there is an assignee)
10. ☐ English Translation Document (if applicable)
11. ☒ Information Disclosure Statement/PTO-1449 ☒ Copies of IDS Citations
12. ☐ Preliminary Amendment
13. ☒ Acknowledgment postcard
14. ☒ Certificate of Mailing
- ☐ First Class ☒ Express Mail (Specify Label No.): EM469880804US

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Accompanying Application Parts (Continued)

15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*

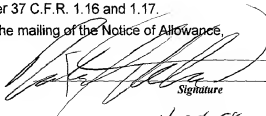
16. ☐ Additional Enclosures *(please identify below):*

Fee Calculation and Transmittal

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	32	- 20 =	12	x \$22.00	\$264.00
Indep. Claims	8	- 3 =	5	x \$82.00	\$410.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
BASIC FEE					\$790.00
OTHER FEE (specify purpose) Recorded Assignment filing fee					\$40.00
TOTAL FILING FEE					\$1,504.00

- ☐ A check in the amount of _____ to cover the filing fee is enclosed.
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NEW APPLICATION TRANSMITTAL

*In re Application of: David L. Thompson

Title: WORLD WIDE PATIENT LOCATION AND DATA TELEMTRY FOR IMPLANTBLE MEDICAL DEVICES

CERTIFICATE UNDER 37 CFR §1.10: I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service, in an envelope addressed "EXPRESS EM469880804US, addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on day of November 24, 1998.

Kathleen A. Paron

Printed Name

Signature

BOX NEW APPLICATION

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

We are transmitting herewith the attached:

☒ Patent Application Transmittal (Duplicate)
☒ Patent Application (In English) ☒ Original Specification 33 sheets 10 claims sheets 1 Abstract Cover page 1 sheet
☒ 9 sheets drawings (informal)
☒ Information Disclosure Statement PTO form 1449 with cited references copy International Search Report
☒ Combined Declaration and Power of Attorney (signed) (2)
☒ Assignment with Cover sheet (3 pages)
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FEE CALCULATION

	No. of Claims Filed	Claims Included in Base Fee	No. of Extra Claims	Rate	Fee
Total Claims	- 32	20	= 12	x 22	264.00
Independent Claims	8	3	= 5	x 82	410.00
Multiple Dependent Claims	No 1				\$
Basic Filing Fee					\$ 790
TOTAL					\$1,504

☒ Charge Deposit Account No. 13-2546 the sum of \$ 1,504.00 (Filing Fee) plus \$40.00 (recordal Fee) for a month Extension of Time fee FOR A **TOTAL OF \$ 1,544.00**

☒ Please charge any additional fees or credits to Deposit Account No. 13-2546 which may have been overlooked on this New Application Transmittal with regard to this filing. A duplicate of this transmittal is enclosed.

11-24-98
Date

Michael B. Atlass
Reg. No. 30,606
MEDTRONIC, INC.
7000 Central Avenue N.E.
Minneapolis, Minnesota 55432
Telephone: (612) 514-3066

APPLICATION FOR UNITED STATES LETTERS PATENT

for

**WORLD WIDE PATIENT LOCATION AND DATA TELEMETRY SYSTEM FOR
IMPLANTABLE MEDICAL DEVICES**

by

David L. Thompson

ATTORNEY OF RECORD:

Michael B. Atlass
Attorney Registration No.30,606
MEDTRONIC, INC.
7000 Central Avenue N.E.
Minneapolis, Minnesota 55432
Telephone: (612) 574-3066
Facsimile: (612) 574-3233

CERTIFICATE OF EXPRESS MAIL

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Washington D.C. 20231


Kathleen A. Paron

WORLD WIDE PATIENT LOCATION AND DATA TELEMETRY
SYSTEM FOR IMPLANTABLE MEDICAL DEVICES

FIELD OF THE INVENTION

5 The present invention relates to communication systems for communicating with an implanted medical device or device system, and more particularly, such a communication system that may function on a world wide basis at any time to communicate patient location, device monitoring data, device re-programming data and to allow for effective response to emergency conditions.

10 The following references were cited in commonly assigned, U.S. Patent 5,683,432 for ADAPTIVE, PERFORMANCE-OPTIMIZING COMMUNICATION SYSTEM FOR COMMUNICATING WITH AN IMPLANTABLE DEVICE by S. Goedeke et al. to indicate the prior state of the art in such matters. In particular, in reed switch use U.S. Patent No. 3,311,111 to Bowers, U.S. Patent No. 3,518,997
15 to Sessions, U.S. Patent No. 3,623,486 to Berkovits, U.S. Patent No. 3,631,860 to Lopin, U.S. Patent No., 3,738,369 to Adams et al., U.S. Patent No. 3,805,796 to Terry, Jr., U.S. Patent No. 4,066,086 to Alferness et al.; informational type U.S. Patent 4,374,382 to Markowitz, U.S. Patent No. 4,601,291 to Boute et al.; and system U.S. Patent No. 4,539,992 to Calfee et al., U.S. Patent No. 4,550,732 to
20 Batty Jr., et al., U.S. Patent No. 4,571,589 to Slocum et al., U.S. Patent No. 4,676,248 to Berntson, U.S. Patent No. 5,127,404 to Wyborny et al., U.S. Patent No. 4,211,235 to Keller, Jr. et al., U.S. patents to Hartlaub et al., U.S. Patent No. 4,250,884, U.S. Patent No. 4,273,132, U.S. Patent No. 4,273,133, U.S. Patent No. 4,233,985, U.S. Patent No. 4,253,466, U.S. Patent No. 4,401,120, U.S.
25 Patent No. 4,208,008, U.S. Patent No. 4,236,524, U.S. Patent No. 4,223,679 to Schulman et al., U.S. Patent No. 4,542,532 to McQuilkin, and U.S. Patent No. 4,531,523 to Anderson.

BACKGROUND OF THE INVENTION

30 Over the years, many implantable devices have been developed to monitor medical conditions and deliver therapy to a patient. Such devices included electrical stimulation devices for stimulating body organs and tissue to evoke a response for

enhancing a body function or to control pain, and drug delivery devices for releasing a drug bolus at a selected site. Other more passive implantable and wearable medical devices have been developed for monitoring a patient's condition.

We will refer to devices that are implantable as IMD's or simply MD's to indicate that they may be implantable or wearable. We will occasionally also refer to the device having GPS and transmitter for keeping in touch with the medical network or satellites as a belt worn device or simply a belt device, although it is understood that the requirement for the device is proximity to the patient with the medical device, (the IMD or MD), meaning it can be worn as a pendent, on the neck, wrist, ankle, or the like.

Chronically implanted cardiovascular devices for monitoring cardiovascular conditions and providing therapies for treating cardiac arrhythmias have vastly improved patients quality of life as well as reduced mortality in patients susceptible to sudden death due to intractable, life threatening tachyarrhythmias. As implanted device technology has grown more sophisticated with capabilities to discover, monitor and affect more patient conditions (including otherwise life threatening conditions) patients have enjoyed freedom from hospital or home confinement or bed rest. However, the improved mobility brings with it the need to maintain communications with the patient and the implanted device.

Early in the development of cardiac pacemakers, patient follow-up to monitor pacemaker operation was facilitated by telephonic transmissions of skin surface ECGs in real time to a physician's office employing such systems as the MEDTRONIC® TeleTrace® ECG transmitter. Over time, various patient worn, ambulatory ECG and device monitors have been developed for providing ECG data for remote analysis of cardiac arrhythmias. Also, the remotely programmable modes of operation of implantable medical devices increased, and programming methods improved.

In current arrhythmia control devices, (e.g. cardiac pacemakers, and pacemaker-cardioverter-defibrillators) a relatively wide range of device operating modes and parameters are remotely programmable to condition the device to diagnose one or more cardiac arrhythmia and deliver an appropriate therapy. In

cardiac pacemakers, the pacing rate in one or both heart chambers is governed by algorithms that process the underlying cardiac rhythm as well as physiologic conditions, e.g. patient activity level and other measured variables, to arrive at a suitable pacing rate. The pacemaker operating modes and the algorithm for calculation of the appropriate pacing rate are programmed or reprogrammed into internal memory by accessing the implanted pacemaker's telemetry transceiver with an external programmer. Even the diagnosis of a tachyarrhythmia requiring delivery of a treatment therapy and the therapies to be delivered may now be governed by operating modes and algorithm parameters that can be programmed into and changed using such a programmer.

Such implanted devices can also process the patient's electrogram and any measured physiological conditions employed in the diagnosis and store the data, for subsequent telemetry out on interrogation by the external programmer. The telemetered out data is analyzed and may be employed to establish or refine the operating modes and parameters by a doctor to adjust the therapies the device can deliver. In general, the manner of communicating between the transceivers of the external programmer and the implanted device during programming and interrogating is referred to as telemetry.

Initially, when programming techniques were first devised, the paramount concern addressed related to patient safety. Safeguards addressed the concern that the patient could be put at risk of inadvertent mis-programming of the implanted device, e.g. by stray electromagnetic fields. For this reason, and in order to avoid high current consumption that would shorten the implanted device battery life, telemetry operating range was extremely limited. In systems continuing to the present time, telemetry has required application of a magnetic field at the patient's skin over the implanted device to close a reed switch while RF programming or interrogating commands are generated to be received by the implanted device transceiver. The programming or interrogating commands are decoded and stored in memory or used to trigger telemetry out of stored data and operating modes and parameters by the implanted device transceiver.

As stated at the outset, one of the rationales and attributes of implanted medical devices of the type described, is that the patient is allowed to be ambulatory while his medical condition is monitored and/or treated by the implanted medical device. As a further safety precaution, "programmers" (devices capable of programming all the operating modes or functions of the implanted device and for initiating interrogation through the telemetry system) are generally not provided to the patients. Patients are periodically examined and device interrogation is conducted by the physician using the external "programmer" during follow-up visits to the physicians office or clinic. This limits the frequency of monitoring and may require certain patients to remain close to the physician's office, and/or limit their life style options (i.e., remain in or near their home).

Emergency conditions (device failure, physiologic variable changes resulting in inappropriate therapy, transient conditions/problems) may require additional monitoring or follow-up.

The short range of conventional device telemetry is itself viewed as unduly limiting of a patient's mobility. In the medical monitoring field, longer range, continuously accessible telemetry has been sought and systems for doing so have been proposed. In U.S. Patent No. 5,113,869 for example, an implanted ambulatory ECG patient monitor is described that is provided with longer range telemetry communication with a variety of external accessory devices to telemeter out alarm signals and ECG data and to receive programming signals. The high frequency RF signals are encoded, including the implanted device serial number, to ensure that the communication is realized only with the proper implanted device and that it is not mis-programmed.

Telemetry communication with other implanted devices, particularly drug infusion pumps or pacemaker-cardioverter-defibrillator devices, to initiate or control their operation is also disclosed. Communication between the implanted AECG monitor and an external defibrillator is also suggested through low current pulses transmitted from the defibrillator paddles through the body link in order to condition the implanted AECG monitor to provide telemetry signals to the external defibrillator.

One of the external devices disclosed in the '869 patent is a wrist worn, personal communicator alarm for responding to a telemetered out signal and emitting a warning to the patient when the implanted AECG monitor has detected an arrhythmia. The patient is thereby advised to take medications or contact the physician or to initiate external cardioversion. The personal communicator alarm also includes a transceiver and may also be used to control certain functions of the implanted AECG monitor. A further, belt worn "full disclosure recorder" is disclosed with high capacity memory for receiving and storing data telemetered out of the implanted AECG monitor when its memory capacity is exhausted.

A remote, external programmer and analyzer as well as a remote telephonic communicator are also described that may be used in addition to or alternately to the personal communicator alarm and/or the full disclosure recorder. The programmer and analyzer may operate at a distance to the implanted AECG monitor to perform programming and interrogation functions. Apparently, the implanted AECG may automatically transmit a beacon signal to the programmer and analyzer to initiate an interrogation function to transmit data to the programmer and analyzer on detection of an arrhythmia or a malfunction of the implanted AECG monitor detected in a self-diagnostic test. Or by setting a timer in the personal communicator alarm, the implanted AECG monitor may be automatically interrogated at preset times of day to telemeter out accumulated data to the telephonic communicator or the full disclosure recorder. The remote telephonic communicator may be part of the external programmer and analyzer and is automatically triggered by the alarm or data transmission from the implanted AECG monitor to establish a telephonic communication link and transmit the accumulated data or alarm and associated data to a previously designated clinic or physician's office through a modem.

The combination of external devices provided to a given patient is at the discretion of the physician. It is preferred that at least the patient be provided with the external programmer and analyzer including a communications link.

A similar programmer/interrogator for an implanted pacemaker-cardioverter-defibrillator device is disclosed in U.S. Patent No. 5,336,245, wherein the data

accumulated in the limited capacity memory implanted device is telemetered out to a larger capacity, external data recorder. The accumulated data is also forwarded to a clinic employing an auto-dialer and FAX modem resident in a personal computer-based, programmer/interrogator.

5 In each of these disclosed systems, presumably, the patient is able to communicate with the physician's office or clinic contemporaneously with the transmission of data by modem. In all such telemetry systems for programming an operating mode or parameter or interrogating accumulated patient data or device operating modes and parameters, the patient is located within a short range, typically within sight, of the remote devices, particularly the remote programmer. 10 If the patient is out of range of the programmer and an attached telephone system, the security of the patient is diminished. Consequently, at risk patients are advised to remain close by to the programmer and telephone for their safety.

The performance over time of implanted medical devices in the implant 15 population is informally monitored by the periodic patient follow-ups employing the telemetry system conducted by the physician and the reporting of device malfunctions from the physician to the device manufacturer. Moreover, operating algorithm improvements developed over time to counter adverse device performance reports or to simply improve device function are provided to 20 physicians to employ in re-programming the implanted devices at the next patient follow-up.

Although significant advances have been made in allowing patient's who are dependent on implanted medical devices to be ambulatory and still allow for monitoring of the device operation or the patient's underlying condition, a need 25 remains to expand patient security while allowing the ambulatory patient to range widely. Telemetry systems in current use require prepositioning of the telemetry head over the implanted medical device, although the telemetry systems described above may offer the possibility of telemetry at a distance of several meters. In any case, such telemetry systems cannot communicate patient device information (uplink telemetry) or accept re-programming (downlink telemetry) when the patient is in 30 remote or unknown locations vis-à-vis the physician of medical support network. In

certain patient conditions, the inability to communicate with the medical implant can significantly increase patient mortality or cause serious irreversible physical damage.

SUMMARY OF THE INVENTION

5 It is therefore an object of the present invention to provide a patient data communication system for world wide patient location and data and re-programming telemetry with a medical device implanted in the patient.

10 It is a further object of the present invention to address the above described problems by providing such a communication system allowing the device and/or patient to communicate with support personnel at any time and from any place.

It is a still further object of the invention to allow the medical device and patient to be accurately and automatically located enabling prompt medical assistance if necessary.

15 These and other objects of the invention are realized in a first aspect of the invention in a system for communicating patient device information to and from a medical device implanted in an ambulatory patient and with a remote medical support network comprising: an implanted device telemetry transceiver within the implanted medical device for communicating data and operating instructions to and from the medical device in a coded communication, the implanted device telemetry
20 transceiver having a transceiving range extending outside the patient's body a predetermined distance sufficient to receive and transmit coded telemetry communications at a distance from the patient's body; and an external patient communications control device adapted to be located in relation to the patient within the device transceiving range having a system controller for facilitating
25 communications, an implant wireless interface including a control device telemetry transceiver for receiving and transmitting coded communications between the system controller and the implant device telemetry transceiver, a global positioning system coupled to said system controller for providing positioning data identifying the global position of the patient to the system controller; communications means
30 for communicating with the remote medical support network; and communications network interface means coupled to the system controller and the communications

means for selectively enabling the communications means for transmitting the positioning data to the medical support network and for selectively receiving commands from the medical support network.

5 Preferably the system further comprises an external patient communications device adapted to be located in relation to the patient within the device transceiving range for providing patient voice and data communications with the system controller, so that patient voice communications may be effected through the communications interface means and the communications means with the remote medical support network.

10 Furthermore, the communications interface means may effect two-way communication of voice and/or data between the remote medical support network and the patient communications device and implanted device telemetry transceiver by inclusion of cards for accessing one or all of the communications means including a cellular telephone network and a satellite-based telecommunication
15 network, a hard-wired telephone communications system and/or a hard-wired interface for computer based system for local area and for modem-based e-mail communications systems. The cards are preferably interchangeable to fit the application needed by the particular patient.

20 The communications interface means preferably include two-way voice communications between the patient and the medical support network and two-way data communications for selectively receiving interrogation or programming commands from the medical support network to interrogate or program the operation of the device operation and to interrogate patient location.

25 The present invention allows the residential, hospital or ambulatory monitoring of at-risk patients and their implanted medical devices at any time and anywhere in the world. The medical support staff at a remote medical support center may initiate and read telemetry from the implanted medical device and reprogram its operation while the patient is at very remote or even unknown locations anywhere. Two-way voice communications with the patient and
30 data/programming communications with the implanted medical device may be initiated by the patient or the medical support staff. The location of the patient and

the implanted medical device may be determined and communicated to the medical support network in an emergency. Emergency response teams can be dispatched to the determined patient location with the necessary information to prepare for treatment and provide support after arrival on the scene.

Enhancements available due to technological improvement are included to provide additional benefits to what was available in US Patent No. 5,752,976 from which these stem.

These improvements include enhancements to the ability to locate the user of the inventive device by dynamic relative location (also called dynamic relative navigation), time slicing of patient device signals to the provider network to improve the normal, non-emergency communications features, clock updating in the patient devices using high accuracy clock signals available from the satellite systems used in GPS which can enhance the fine granularity of available time slicing of patient device communications signals, the use of Enhanced 911 (called E-911, which will permit triangulation on the cell phone callers location through the E-911 system) or other emergency telephone systems (including current 911 systems), dead reckoning , improved GPS systems like DGPS, reporting changed location if a larger than some predetermined distance is traversed by the patient device, cell phone triangulation and emergency location , all to supplement contact location information, and the transmission of raw data to be position calculated at remote or emergency vehicle locations.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects, advantages and features of the present invention will be more readily understood from the following detailed description of the preferred embodiments thereof, when considered in conjunction with the drawings, in which like reference numerals indicate identical structures throughout the several views, and wherein:

Figure 1 is block level diagram of a first variation of the system of the invention for a patient having free ranging mobility including an implantable medical device, a patient communications control device and a medical support

network optionally employing wireless satellite telecommunication and a global positioning satellite receiver;

Figure 2 is a schematic illustration of the system of Figure 1 in relation to a patient;

Figure 3 is block level diagram of a second variation of the system of the invention for a patient having limited mobility including an implantable medical device, a patient communications control device and a medical support network employing conventional wired telecommunication;

Figure 4 is a schematic illustration of the system of Figure 3 in a line powered monitor for use in a patient's hospital room;

Figure 5 is a schematic illustration of the system of Figure 3 employing a patient-worn, communications link and a line powered monitor for use in a patient's home; and

Figure 6 is a block diagram of an exemplary implanted medical device with which the invention may be practiced.

Figure 7 is a schematic diagram of the main component communicating parts for preferred embodiments of this invention.

Figure 8 is also a schematic diagram of the main component communicating parts for preferred embodiments of this invention, as adapted to help in quick location of patients.

Figure 9 is a block circuit diagram of components useful for maintaining a relative to last GPS address location, in accord with a function of this invention.

Figure 10 is a flow chart of steps for coordinating time slice reporting of device status in accord with a feature of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The Global Communications and Monitoring System (GCMS) of the present invention provides a means for exchanging information with and exercising control over one or more medical devices implanted within the body of a patient employing the patient communications control device. The GCMS in its most comprehensive form of Figures 1 and 2 is intended to function no matter how geographically remote the patient may be relative to the monitoring site or medical support

network. In this form, the GCMS provides an alarm to notify the medical support network should device or patient problems arise, determines patient location via the Geopositioning Satellite System (GSS), and allows verbal communication between the patient and monitoring personnel via a cellular telephone system link (if available at the patient location) or a satellite based telecommunications link if the patient is outside the range of a cellular link or subscribes only to the satellite-based link.

Improvements in technology are now available since the filing of the parent applications hereto that allow for enhancement of the features first described. Also, some additional problems and opportunities have been identified and addressed in this application. The improvement in GPS accuracy provided by DGPS systems and the development of cell phone location techniques have provided new opportunities to enhance patient location. The fact that behind some barriers, like trees, buildings, and so forth block some GPS signals has provided the inventor to improve the original disclosure. Likewise, some new thinking about how to improve the ability to find patients, including dead reckoning intelligence being added to the patient devices and use of time slice updates to the medical provider system have increased the usefulness of the invention.

The system is not intended to be limited to such remote use by a free ranging patient and is intended to also be used when the patient is less mobile. In the sub-system or second variation illustrated in Figures 3-5, the patient communication control device is intended to be coupled to a telephone or other communications system for a patient with more limited mobility. For example, the standard telecommunications system may be accessed either through a hard-wired link or by a cordless telephone with a telephone receiver in the room attached to a phone jack. In this case, the cellular or satellite-based telecommunications interface capabilities are not necessary, and the GSS capability may be superfluous.

Preferably, the GCMS of Figure 1 includes all of these capabilities embodied in a patient communications control device that is small and light enough to be attached to the patient when the patient is mobile or to be used by the patient as a free standing unit at the patient's residence or hospital room. Alternatively, as

shown in Figures 3-5, the GCMS can be re-configured in part as a stand alone, line powered, room monitor and the remaining part can be implemented as a patient-worn, battery powered, communications link with a transceiver capable of two-way communication between the patient, the implanted medical device and the line powered monitor.

Figures 1 and 3 are intended to show the alternate components of both of the variations of the GCMS, although the alternate components may be included in the same GCMS. The patient 10 has one or more implanted medical devices 12, 14, which in the latter case may communicate with one another is known as, for example, using the body medium in a manner described in commonly assigned U.S. Patent No. 4,987,897 to Funke. The medical device 12 (and associated device 14, if present) may be, for example, an arrhythmia control device, e.g. a cardiac pacemaker or a pacemaker-cardioverter-defibrillator. A relatively wide range of device operating modes and parameters are remotely programmable to condition such a device 12 to diagnose one or more conditions such as cardiac arrhythmias and/or deliver electrical or other stimulus appropriate for therapy. The implanted medical device 12 may alternatively be a drug administration device, cardiomyoplasty device, neural stimulator or any other implantable device with electronic control functions that can be programmed and/or have memory for storing patient and device operating data.

At least one implanted medical device 12 possesses a transceiver of the type known in the art for providing two-way communication with an external programmer. The encoded communication may be by the RF transmission system such as is described in the above-referenced '869 patent or by using spread spectrum telemetry techniques described in U.S. Patent No. 5,381,798 to Burrows or by the system disclosed in the above-referenced U.S. Patent No. 5,683,432 or any of the known substitutes. The telemetry technique employed and the transceiver of the implanted medical device 12 have enough range to communicate between the transceiver in the implant wireless interface 22 in the remote patient communications control device 20 and the implant (12...14). The system disclosed

in the above-referenced U.S. Patent No. 5,683,432 may be employed to increase the accuracy and efficiency of the uplink and downlink telemetry.

Figure 6, depicts an implantable pulse generator (IPG) circuit 300 and atrial and ventricular lead system 112, 114 having programmable modes and parameters and a telemetry transceiver of a DDDR type known in the pacing art as an example of an implanted medical device 12. While described in some detail, this device 12 provides only one example of the kind of implantable device that may be employed with this invention.

The IPG circuit 300 of Figure 6 is divided generally into a microcomputer circuit 302 and a pacing circuit 320. The pacing circuit 320 includes the output amplifier circuit 340 and the sense amplifiers 360. The output circuit 340 and sense amplifier circuit 360 may contain pulse generators and sense amplifiers corresponding to any of those presently employed in commercially marketed cardiac pacemakers for atrial and ventricular pacing and sensing. The bipolar leads 112 and 114 are illustrated schematically with their associated electrode sets 116 and 118, respectively, as coupled directly to the input/output circuit 320. However, in the actual implanted device they would, of course, be coupled by means of removable electrical connectors inserted in a connector block.

Sensed atrial depolarizations or P-waves that are confirmed by the atrial sense amplifier (ASE) in response to an A-sense are communicated to the digital controller/timer circuit 330 on ASE line 352. Similarly, ventricular depolarizations or R-waves that are confirmed by the ventricular sense amplifier in response to a V-sense are communicated to the digital controller/timer circuit 330 on VSE line 354.

In order to trigger generation of a ventricular pacing or VPE pulse, digital controller/timer circuit 330 generates a trigger signal on V-trig line 342. Similarly, in order to trigger an atrial pacing or APE pulse, digital controller/timer circuit 330 generates a trigger pulse on A-trig line 344.

Crystal oscillator circuit 338 provides basic timing clock for the pacing circuit 320, while battery 318 provides power. Power-on-reset circuit 336 responds to initial connection of the circuit to the battery for defining an initial operating

condition and may reset the operative state of the device in response to a low battery condition. Reference mode circuit 326 generates stable voltage and current references for the analog circuits within the pacing circuit 320. Analog to digital converter (ADC) and multiplexor circuit 328 digitizes analog signals. When
5 required, the controller circuit will cause transceiver circuit 332 to provide real time telemetry of cardiac signals from sense amplifiers 360. Of course, these circuits 326, 328, 336, and 338 may employ any circuitry similar to those presently used in current marketed implantable cardiac pacemakers.

Data transmission to and from the external programmer of the patient
10 communications control device of the preferred embodiment of the invention is accomplished by means of the telemetry antenna 334 and an associated RF transmitter and receiver 332, which serves both to demodulate received downlink telemetry and to transmit uplink telemetry. Uplink telemetry capabilities will typically include the ability to transmit stored digital information, e.g. operating
15 modes and parameters, EGM histograms, and other events, as well as real time EGMs of atrial and/or ventricular electrical activity and Marker Channel pulses indicating the occurrence of sensed and paced depolarizations in the atrium and ventricle, as is well known in the pacing art. The IPG transceiver system disclosed in the above-referenced U.S. Patent Number 5,638,432 may be employed to
20 provide the uplink and downlink telemetry from and to the implanted medical device in the practice of the present invention.

Control of timing and other functions within the pacing circuit 320 is provided by digital controller/timer circuit 330 which includes a set of timers and associated logic circuits connected with the microcomputer 302. Microcomputer
25 302 controls the operational functions of digital controller/timer 324, specifying which timing intervals are employed, and controlling the duration of the various timing intervals, via data and control bus 306. Microcomputer 302 contains a microprocessor 304 and associated system clock 308 and on-processor RAM and ROM chips 310 and 312, respectively. In addition, microcomputer circuit 302
30 includes a separate RAM/ROM chip 314 to provide additional memory capacity. Microprocessor 304 is interrupt driven, operating in a reduced power consumption

mode normally, and awakened in response to defined interrupt events, which may include the A-trig, V-trig, ASE and VSE signals. The specific values of the intervals defined are controlled by the microcomputer circuit 302 by means of data and control bus 306 from programmed-in parameter values and operating modes.

5 If the IPG is programmed to a rate responsive mode, the patient's activity level is monitored periodically, and the sensor derived V-A escape interval is adjusted proportionally. A timed interrupt, e.g., every two seconds, may be provided in order to allow the microprocessor 304 to analyze the output of the activity circuit (PAS) 322 and update the basic V-A escape interval employed in the
10 pacing cycle. The microprocessor 304 may also define variable A-V intervals and variable ARPs and VRPs which vary with the V-A escape interval established in response to patient activity.

Digital controller/timer circuit 330 thus defines the basic pacing or escape interval over a pacing cycle which corresponds to a successive A-V interval and V-
15 A interval. As a further variation, digital controller/timer circuit 330 defines the A-V delay intervals as a SAV that commence following a sensed ASE and a PAV that commences following a delivered APE, respectively.

Digital controller/timer circuit 330 also starts and times out intervals for
controlling operation of the atrial and ventricular sense amplifiers in sense
20 amplifier circuit 360 and the atrial and ventricular amplifiers in output amplifier circuit 340. Typically, digital controller/timer circuit 330 defines an atrial blanking interval following delivery of an APE pulse, during which atrial sensing is disabled, as well as ventricular blanking intervals following atrial and ventricular pacing pulse delivery, during which ventricular sensing is disabled. Digital
25 controller/timer circuit 330 also defines an atrial refractory period (ARP) during which atrial sensing is disabled or the ASE is ignored for the purpose of resetting the V-A escape interval. The ARP extends from the beginning of the SAV or PAV interval following either an ASE or an A-trig and until a predetermined time following sensing of a ventricular depolarization or triggering the delivery of a VPE
30 pulse as a post-ventricular atrial refractory period (PVARP). A ventricular refractory period (VRP) may also be timed out after a VSE or V-trig. The

durations of the ARP, PVARP and VRP may also be selected as a programmable parameter stored in the microcomputer 302. Digital controller/timer circuit 330 also controls sensitivity settings of the sense amplifiers 360 by means of sensitivity control 350.

5 The illustrated IPG block diagram of Figure 6 is merely exemplary of one form of an implanted medical device 12 having a telemetry transceiver. The telemetry transceiver 332 is capable of receiving interrogation commands for uplink telemetry of accumulated data, e.g. stored histograms of intracardiac electrograms (IEGM) or other electrogram (EGM) data maintained in RAM 310 or RAM/ROM unit 314, or of real-time data, e.g. the raw EGM of the patient's heart. In addition, it is capable of receiving permanent reprogramming commands or certain temporary programming commands for changing operating modes or parameters of the IPG 300 to counter a condition diagnosed by the medical support network. In this manner, the selective initiation of the operation of the therapeutic treatment (pacing for device 12) and monitoring can be effected through operating commands received by said implanted device telemetry transceiver 322. Furthermore, the operating algorithms governing the various pacing modes or parameters of those operating algorithms may be re-checked and altered through downlink interrogation and re-programming. In addition, the normal, periodic follow-up of the IPG 300 operation can be remotely initiated and conducted using the uplink and downlink telemetry between the transceiver 332 and the implant wireless interface under the control of the system controller as described below. The present invention can therefore readily be practiced using the basic hardware of existing microprocessor-controlled, dual chamber pacemakers, pacemaker-cardioverter-defibrillators and other medical devices, with a transceiver capable of uplink and downlink telemetry at a distance of up to several meters between the telemetry antenna 334 and the external telemetry antenna of the patient communications control device 20 or 20' of the variations of the present invention.

Returning to Figures 1 and 3, the patient communications control device 20, 20' therefore includes the implant wireless interface 22 that operates as a two-way telemetry transceiver for communicating with the telemetry transceiver of the

implanted medical device 12 or devices 12, 14 and is controlled in those operations by a microcomputer-based system controller 24, preferably a 486XX microprocessor with RAM and ROM, e.g. the Cardio 486 available from SMOS SYSTEMS located in San Jose, California maybe employed as the controller 24.

5 The system controller 24 contains a system clock for maintaining an accurate time base which in one embodiment may be recalibrated periodically via accurate clocks in the GPS satellites 62. The microcomputer-based system controller 24 is coupled to the patient link 26 and the voice and data communications network interface 28 via voice and data buses 36 and 38. A patient link 26 provides a microphone and speaker through which the patient 10 can use for voice communication through the system controller 24 and the voice and data communications network interface 28 with the remote medical support network 50. Communication between the system controller 24 and the communications interface 28 is via data and voice buses 44 and 46. The system controller 24 may be part of a standard or modified cellular telephone or other personal communication device and may simply recognize specific telemetered signals from the implanted device if desired.

15 At the medical support network 50, a base station is provided to be in the communication link with the monitor 30 or the patient-worn communications device 40. The base station is preferably a microprocessor-based system that includes the software and hardware needed for voice communication with the patients to locate the patient and to interrogate and program the implanted medical devices using the communications interface links incorporated into the GCMS. Alternatively, a system can employ a device similar to the base station as a mobile unit in an emergency vehicle like an ambulance or helicopter as illustrated in Fig. 7, vehicles 25 105 and 105a.. This mobile unit being tasked to find the exact location of a patient in an alarm condition and to rapidly administer medical aid and provide transportation to the most appropriate medical center.

30 Patient voice communications through the patient link 26 include both actual patient voice and/or manually actuated signaling which may convey an emergency situation. For example, a patient may initiate communications through link 26 by depressing a button and/or speaking into the microphone/speaker. The patient voice

is converted to an audio signal, digitized, encoded and transmitted either by voice bus 36 or by a transceiver in the case where the patient link 26 is physically separated from the system controller 24, as described below. The patient activated emergency signal is likewise encoded and transmitted by data bus 38 or its equivalent transceiver encoded RF signal to the system controller 24.

Patient link 26 is a custom designed circuit that preferably has a microphone and speaker, associated drivers, a visual indicator (i.e. light or LCD display), and a patient activator. In the embodiment where the patient link 26 is physically part of the patient communications control device 20, the patient link also includes interface circuitry to buses 36 and 38 as shown in Figure 1. Alternatively, the patient link 26 can be combined with the implant wireless interface as a combined PCMCIA (or other communications) card and a single data bus may be shared between the two circuits. In a further embodiment having a physically separated and separately powered patient communications control device 26, the voice and data buses 36 and 38 can be replaced by short-range wireless LAN PCMCIA cards at each end of the link. An infrared wireless LAN PCMCIA adapter with an integrated transceiver, Model No. 87G9743, is currently available from IBM, Inc., Somers, New York. An RF wireless LAN PCMCIA adapter with an integrated transceiver, Model No. 80G0900 is also available from IBM, Inc., Somers, New York. Other similar devices may be used.

Much improved location finder systems are available from Trimble Navigation and Leica as described below, and these could of course be used to effectuate the improved location of and contacting of the patient system. For most situations basing the receiver on the DGPS in the AgGPS 132 from Trimbal would be sufficient, but including the signal interference capabilities of the 4000rsi and Dsi devices may prove advantageous. By incorporating or using these or even the Leica systems now available to determine location to a claimed 1cm accuracy, sending the location information from the patient to the emergency locator vehicle could aid in locating a patient more quickly by indicating the direction and distance to that location in the emergency vehicle's base/mobile station display(one example

illustrated in Fig. 8. (Citations for Trimbal and Leica are near the end of this application).

Continuing specifically with the first variation of Figures 1 and 2, these figures depict the components of the more comprehensive GCMS of the present invention for allowing greater patient mobility, a wider range of communications network interface links and the capability of locating the patient anywhere in the world. In the GCMS of Figure 1, all components of patient communications control device 20 are incorporated into the patient-worn communications device 40 which may be worn, for example, on a patient's belt or carried in a pocket, or worn on a wrist. Alternatively, as described above, the patient link 26 may be separated into a wrist-worn device having a separate transceiver for convenience of use in voice communication. In any event, the emerging Personal Communications System (PCS) technology may be employed in the miniaturization of the system components.

In accordance with one aspect of the invention, the system controller 24 is coupled to a GPS receiver 60 via bus 58 for receiving patient positioning data from an earth satellite 62. The GPS receiver 60 may use current systems such as the Mobile GPS™ (PCMCIA GPS Sensor) provided by Trimble Navigation, Inc. of Sunnyvale, California or Retki GPS Land Navigation System provided by Liikkura Systems International, Inc. of Cameron Park, California, or other similar systems. The GPS receiver 60 may be actuated by a command received through the system controller 24 from the medical support network, in the case of an emergency response. In the case of a non-emergency, periodic follow-up, the GPS receiver 60 may be enabled once an hour or once a day or any other chosen interval to verify patient location. The determined location may be transmitted to the medical support network and/or stored in RAM in the system controller 24. To maintain patient location information in the absence of GPS signals (such as inside metal buildings), a three-axis accelerometer 72 or other position/motion determining device can be incorporated into the system. By knowing original position (from the last valid GPS point), time (from the internal clock) and acceleration (motion),

patient position can be calculated from the three axis coordinates realized from each accelerometer output calculated in each case from:

$$x(t) = x(0) + v(0)t + \iint a(t)dt$$

where $x(0)$ is the initial position stored in memory for each axis, t is time, a is acceleration and v is velocity.

In the free ranging embodiment of Figures 1 and 2, two communication network interface links with the medical support network 50 are included, although the communication interface links of the second variation of Figures 3-5 may be included for optional home use. One non-hard-wired communication interface link is effected through the soon to be deployed, worldwide satellite communications system, called "Iridium", by Motorola, Inc. of Schaumburg, Illinois. This is a PCMCIA card 64 which may be built from common components by one skilled in the art. Another (second) communications link can be effected by the ARDIS (Advanced Radio Data Information Service) pocket radio communications network via PCMCIA link card 66, a Mobidem modem available from Ericsson, Inc. of Raleigh, North Carolina. Both of the radio links operate as modems with voice and data simultaneously transmitted via adding the CT8020 (DSP Group of Santa Clara, California) to a standard data modem such as a 28.8 Keepintouch™ Express modem from AT & T Corp. of Largo, Florida.

Either or both PCMCIA cards 64 and 66 may be provided and they are coupled with the voice and communications network 28 via buses 68 and 70, respectively. When both are provided, access to the communications satellite link 80 is automatically obtained when a link to a cellular transceiver 82 is not possible.

It should be noted that "Iridium" manages cellular location of each subscriber in the network at all times. The subscriber unit, which in this invention would be incorporated into the device 20 (or communicatively connected to it) identifies itself and its location on a periodic basis to the system manager. In any system chosen it is expected that the control and communications device will have to report in to a management system regarding its location on a periodic or at least

on a changed location basis or both. The implanted device need not be concerned about this activity and need not use any of its battery power to accomplish it since only the external device 20 (in the preferred embodiments) needs to be involved in such location communication. Only by knowing the patient location can the medical system 50 communicate to the implanted device at any time it wants or needs to. Accordingly, if emergency communications are expected short intervals between reporting in are recommended.

By checking in, the patient's external communications device would act like a cellular phone, answering incoming medical system messages broadcast into the cell in which it is located.

For patient convenience, a personal communicating device may incorporate the controller/communicator that communicates between implanted device(s) and the external world. In this way it could look like and operate as a personal communicator or cellular phone and reduce patient psychological discomfort. It should also be recognized that if the cellular telephone system manages all communication functions between the outside-the-patient-system and the medical community system, the implanted device need only be able to communicate with the cellular communications product.

Figure 2 illustrates the free ranging patient 10 located remotely from the medical support network 50 and from any hard-wired communications link. The patient communications control device 20 is implemented in the belt-worn portable unit 40, although the patient link 26 may be worn separately on the patient's wrist (not shown). Alternatively, the patient communications control device 20 including the patient link 26 may be packaged into a portable telephone configuration and carried in a pocket. In any embodiment, the patient location may be determined by communications with the GPS 62. The voice and data communications link with the medical support network 50 may be effected by a cellular phone link including transceiver 82. Alternatively, the voice and data communications link may be effected using the communications satellite link 80.

The patient communications control device 20 of Figures 1 and 2 is powered by a battery power supply 74 that preferably is rechargeable, or alternatively by

commonly available batteries of any type. The system controller 24 includes a power control system for powering down the microprocessor and the associated components of the patient communications control device 20 except on receipt of an interrupt in a manner well known in the art.

Power consumption can be significantly reduced by powering up the communication and satellite circuitry periodically for a short period of time to re-acquire a GPS location and/or look for requests for data or status from the medical support network 50. This system power consumption reduction can greatly enhance battery lifetime requiring less frequent battery replacement or recharging, in the case of a rechargeable battery configuration. As an alternate to using a management system to maintain a patient location data based on patient's device periodic check-in each GCMS system for each patient could have a specific time slot (for example, 30 seconds) non-overlapping with other GCMS systems to power up, acquire location coordinates from the GPS system and be alert for a call from the medical support network 50. Periodically (for example, once per day), the medical support network 50 would reset/recalibrate the system clock in system controller 24 from the atomic clock in the GPS satellite system. This would ensure that no specific GCMS system clock would drift out of range of its allotted time slot and be unavailable for reception or drift into an adjacent time slot. Other time dividing schemes used in other arts may also be employed to maximize battery life for any system.

Time slicing the power up communications can increase the number of available time slots in a local system if the time slices are small and accurately maintained. To do this, the patient's system would simply update it's internal clock with reference to the atomic clock signal broadcast via the satellite to maintain accurate timekeeping for itself.

Turning to the second variation of the invention illustrated in Figures 3-5, it should be noted that the system of Figure 1 may also be used in the home or in the hospital using the cellular communications link card 66. However, the modified patient communications control device 20' of Figure 3 is preferably implemented with the voice and data communications network interface 28 having the capability

of directly linking with a hard-wired phone line 32 or other communication services, which may include a hospital installed network, e.g. a personal computer interface to a local area network. In either case, the modified patient communications control device 20' may be implemented in a number of portable or stationary monitor 30 forms.

In the embodiment illustrated in Figure 4, all of the Figure 3 components of the modified patient communications control device 20' are located in the monitor 30. The patient link 26 and the implant wireless interface 22 are hard-wired by voice and data buses 36, 38 and 42 to the system controller 24. In the embodiment of Figure 5, the patient link 26 and the implant wireless interface 22 are located in the patient-worn communications device 12. The remaining components of the modified patient communications control device 20' are located in monitor 30, and suitable RF telemetry transceiver links are substituted for the buses 36, 38 and 42. In either embodiment, the power supply 74 of the monitor 30 may be line powered. The modified patient communications control device 20' within monitor 30 may also be coupled to a wall jack for hard-wired communications through the phone line 32 or other communications service 34 with a medical support network 50 located remotely or within the hospital.

As described above, implantable devices such as 12... 14 include telemetry transceivers with range suitable for communicating over a short range to the implant wireless interface 22 of the modified patient communications control device 20' within stand alone monitor 30. This remote link offers advantages over patient-worn electrodes or programming heads required in the standard skin contact telemetry and monitoring used at present. Skin contact is difficult to maintain, as the adhesive for the electrodes or heads fails in time, skin irritation is often a problem and inadvertent removal of electrodes is also prevalent. Moreover, the EGM and other body condition monitoring capabilities of advanced implanted medical devices can be taken advantage of to substitute for in-hospital monitoring, e.g. Holter monitoring of the patient's electrogram. The electrogram and/or other sensor derived data, e.g. pressure, temperature, blood gases or the like, stored by the implanted device can be transmitted out continuously or on periodic automatic

telemetry command and sent by the communications link to the remote or hospital medical support network 50.

In either environment of Figure 4 or 5, the patient 10 may communicate with the medical support staff at the medical support network 50 through the voice channel provided in the patient link 26. The patient communications control device 20 or 20' in either embodiment can retrieve all implanted device stored patient and device operating data on receipt of a command from the medical support network 50, process and temporarily store such data, and transmit it back to the support network 50 for analysis. Moreover, implanted devices 12...14 may be reprogrammed from the medical support network 50 to alter device operating modes and parameters employing the modified patient communications control device 20' as a programmer. Finally, the modified patient communications control device 20' can transmit an alarm to the medical support network should there be problems with the patient or implanted devices 12, 14. For example, the implanted devices 12, 14 may signal a low battery condition or a low drug supply in the case of an implanted drug dispenser or other problems found in self-diagnostic routines periodically conducted within the implanted devices 12...14.

The variations and embodiments of the GCMS of the present invention provides comprehensive monitoring of implanted medical devices independent of the geographic mobility of the patient using the devices, obviating the need for the patient to return to a designated follow-up monitoring site or clinic. Moreover, it allows determination of the patient's geographic location via the GSS 62 while providing simultaneous two-way communication with devices and the patient when desired.

In addition to emergency response and routine patient management, the GCMS facilitates medical device clinical studies, providing data collection at one central site from all study patients without requiring their active involvement or clinic visits. This is especially useful for conducting government-mandated post-market surveillance studies. Should there be need to upgrade or change the behavior of implanted devices the global system allows a central monitoring site to revise all involved implants anywhere in the world by transmitting new

programming instructions to every device (assuming appropriate governmental authorities and the patients' physicians have agreed to the need for such changes). The patient need not be directly involved in this updating and need not be aware of the actual process.

5 A continuous and automatic medical monitoring service could be implemented to shorten response time for emergency medical situations or device events signifying patient difficulty. For example, a patient having an implanted cardioverter/defibrillator may be subjected to multiple defibrillation shocks, due to an underlying arrhythmia that cannot be converted by the shocks. To achieve this
10 in the first variation of Figures 1 and 2, the implanted medical device 12 or 14 would initiate an emergency transmission to the patient communications control device 20 which would contain, but not be limited to, all or some of the following: patient name and mailing address, patient's current location, patient's current medical condition requiring assistance, ongoing "real time physiological variables",
15 patient medical support team information, and current status (patient and device) and data stored within the implanted medical device. The patient communications control device 20 would obtain the GSS signal and transmit all the information to the medical support network 50. The patient may also transmit voice information if conscious of the event. A similar response to an emergency situation can be
20 initiated and completed in the GCMS of the second variation using the modified patient communications control device 20'. And, as mentioned before, the time slice can be very small for each patient in a local provider network if the system checks its time clock against the atomic clock time signals available from the satellite.

25 Moreover, patient follow-up and periodic monitoring (i.e. monthly, quarterly, etc.) of the medical implant's stored data and status could be done automatically and be completely transparent to the patient. The medical support team would even have the capability of changing the implanted device settings or programming with complete transparency to the patient (or alternatively, voice or
30 warning signals may be used to identify impending programming).

Interactions with the implanted device and patient may be totally transparent to the patient, e.g., routine location checks to determine if the patient is in proximity sufficiently with the patient communications device to interrogate the implanted device or for follow-up data collection from the implanted device's monitoring memory or reprogramming of operations of the device effected at night while the patient sleeps. Or the patient may be included in the process, even to the extent that voice communications from the staff at the support network to instruct or reassure the patient are received in the patient communications control device.

The following chart details the communications pathways and the data that can travel over them are detailed in the following chart.

Medical Device(MD) Data to Belt Device	a. Serial No. or other unique ID data b. Patient Condition c. Device status data d. Device Sensor data e. Coordinating data
Belt Device to Medical Device(MD)	a. Commands to MD(change a program parameter/value/sequence, interrogate, request a program or data, etc.) b. Coordinating data (ex.. outside pressure)
Network Data to Belt Device	a. Commands to Belt Device or MD b. Coordinating data(ex. DGPS)
Belt Device to Network	a. Belt Device data (which includes all data from the MD and Belt Device generated data including Dynamic Relative Reference, and GPS and DGPS as required or requested.)

NOTES: Wake-ups, acknowledgments, protocol, error correcting, and handshaking all as designed for each component to component communication.

It should be noted that Network includes for example any number of nodes in a telephone system that are part of the health care provider network, or any specific one of such nodes.

Using these communications features we can enhance the functionality available to the medical community for using these devices, while at the same time providing enhanced location of patients in emergency situations.

In particular, we use the enhancements of the GPS system called DGPS to more accurately identify the patient location. We also use on-board automatic dead reckoning facilities in the belt worn or in the IMD itself to provide update control and location information relative to a last DGPS or GPS location. We also can provide interaction with cellular telephony systems that can now be used to provide location information as well.

To reduce the amount of information processing that has to be done in the belt worn or IMD, we can take advantage of the nature of the GPS data itself.. This data can be represented as follows. The table illustrates a variable length data transmission from the patient communications control device 20 (or 20') to the remote medical support network 50, for example.

DATA TABLE:

Byte	Label	Description
0	Sync flag	A hex value to identify the start to receiver (usually FF)
1-2	Length of Data	integer indication of number of bytes to follow
3-6	Patient ID code	Unsigned long integer value
7-8	GPS FOM	Figure Of Merit, calculated by GPS (integer value, depends on number of satellites in view)
9-10	GPS GDOP	Geometric Dilution of Precision calculated by GPS (integer value, includes the time correction data based on the satellite broadcast atomic clock data)
11-18	GPS Latitude	IEEE double precision format
19-26	GPS Longitude	IEEE double precision format
27-n	ECG/physiologic signal/device status, etc.	number of bits dependent on digitization rate and what data is being sent
n+1	LRC	Longitudinal Redundancy Check data and ECC data to correct errors in transmission.

When using the system to locate patients, the Contact Patient software module contains two identical arrays that form the binary data packets. While one packet is collecting real time data from the ADC 328 of implantable device 300 and the result of a GPS calculation, the other is communicating to the base station . Once every second the packets change function (commonly called double buffering). Real time displayed data is delayed by one second. The actual data transmission time depends on the amount of data, which is set by the digitization rate and the baud rate achieved over the wireless link between devices. Typically the table full of data would be transferred in a third of a second.

Alternatively, to save power in the patient worn belt and IMD devices, the use of the GPS Latitude and Longitude calculations need not be made. These could be calculated in a computer in a rescue vehicle (Fig. 7) or in the hospital, or somewhere else in the system, from raw GPS satellite data and thereby saving power for the small devices. Simply turning off the main GPS receiver activities will save power too, as was demonstrated in U.S. Patent No. 5,592,173, incorporated herein by reference. In this patent as well, a dead reckoning system is also suggested as being useful in the powered down mode.

Referring now to Figure 7, in which a system 100 in accord with one aspect of this invention is shown, a tower 101 base station, broadcasts its correction data from its known location to the devices located in a clinic/hospital 103, a moving rescue vehicle 105 and the patient system 104. There currently are at least two DGPS systems commercially available, one from Trimble Navigation Limited, Sunnyvale California and Hampshire England, and another from Leica Navigation and Positioning of Torrance California and Leica Inc., Norcross Georgia. Both these companies provide base stations for broadcasting and receivers for receiving and correlating GPS and DGPS data that could be useful for the system components shown in Fig. 7, but other similar systems could be used as well. A description of the features providing for DGPS location in the Trimble system are mentioned in the U.S. Patents, 5,777,580, 5,745,868, 5,731,768, and 5,680,140, all of which are herein incorporated by this reference.

The satellite 102 could be any of the GPS satellites, and the hospital or clinic 103 could be any medical facility. The personal system of the patient 104, may be worn for example on a belt or pendant or by other means kept near his body, as preferably two parts, the medical device MD (104a) and the belt worn device consisting of the programmer type communicating module PMD 104b for communicating with the medical device 104a, the telecom unit 104d for communicating with local telephony systems through wireless cell phone type technologies, and the DGPS or GPS unit 104c, which receives the satellite data and data from fixed base stations like station 101.

Referring now to Fig. 8, the belt worn device 104 receives satellite data A, broadcast from a set of satellites 102a-n (only one is pictured). It also receives broadcast correction data signals A' from a base station 101. The finding system in device 106 receives this same data. When alerted to be looking for the location of the patient worn device 104, device 106 will also be looking for information broadcast by device 104 in signal B. Generally this data will include information received from the satellites 102a-n that are in range of the belt worn device 104 in a packet 107a and the correction data received from the DGPS base station 101 in packet 107b. From this data the exact location of device 104, can be computed. By computing this location data itself, device 106 can then compute its own location and produce a vector to the device 104 for display (like display 106a) to the user of device 106. It is believed that the most effective display would be a directional arrow with a numeric display of distance units to the device as illustrated, but any combination of numeric, alpha, and illustrative displays as well as audible signaling including speech (for example, the device could say 20 yards to your left for use by a fire fighter in a smoky building) may be used if desired. There is also no reason not to incorporate a telephone receiver for direct communications with the patient in both the devices 104 and 106 if desired.

The data in the interchange between the mobile finding device 106 and the patient belt worn device 104 can be in many forms, but preferably we would use a data format like in the DATA TABLE, above.

Improvements in the flexibility of how to access a patient in distress or for location of any other person using a device such as 140 in Fig. 8 can be had using alternate systems already in use.

For example, in the United States, there is a new FCC proposed rule for broadband personal communications services carriers to comply with section 103 of the Communications Assistance for Law Enforcement Act, so many competing systems for location of cell phones will be available to supplement the finding features of this invention. It is believed that nearly all cell phone systems will be able to locate their users within 15 meters under this initiative. While this initiative is related to law enforcement activities primarily, it's use for medical emergencies should not be proscribed. There is also an initiative to have emergency calls to the Emergency 911 (E911) system from cell phones activate location information for the emergency response services to be more effective. Finally, if the medical device (104a of Fig. 7) notes that its wearer has an emergency condition, it could activate a call by a communication to the PMD com unit 104b to call the 911 or other emergency service (using unit 104d) through the wireless telephone system. An initial location data stream would preferably automatically be sent with the initial call when the call was made, using this new initiative system. This information receiving function could be incorporated into emergency telephone receiving equipment or if the emergency services don't provide it, a voice transmission of the nature of the emergency and perhaps some indication of location could be given by the telecom unit 104d from a bank of recorded message parts to emergency response personnel. If special equipment is incorporated in the emergency telephone communications system, emergency codes could be sent along with the location data or just sent by itself. Also, code data regarding the patient condition, like blood pressure, temperature, battery fault in an implanted device or any other relevant information regarding the patient condition, environment or device status can be reported with the emergency coding.

Time slice updating of the status of a device like that of 104 in Fig. 8, implants 12, 14 etc. and 20 of Fig. 1, or 12 and 30 of Fig. 2, can be effectively

provided to many thousands of patients in a geographic region with little difficulty provided there is accurate keeping of time by all units in a given system.

Fig. 9 illustrates the main internal components needed for keeping track of the patient location if the GPS system is temporarily unavailable, and for using a dead reckoning system to complement the GPS or DGPS systems in any other ways.

There should be a real time clock 901, a microprocessor unit 903 and some memory circuits 902 connected by circuit lines or a bus 904 to the position tracking monitoring circuitry 905. This tracking and monitoring circuitry should also be associated with a gyroscope like device, a minimized inertial navigation system, a multi-axis accelerometer system, or some other mechanism useful to track the movement of the patient in three dimensional space. A number of different systems have been worked out that would be satisfactory for this purpose, and any of these could be chosen. The inertial navigation systems used in modern aircraft provide other examples. Alternatively, the pedal impacts based system described in U.S. Patent No. 5,583,776, hereby incorporated by reference may be used. This will allow for patient location when out of the range of GPS systems and also for rapid restart upon re-entering the GPS or DGPS fields instead of a 10 minute "cold start" which would otherwise be required.

An additional feature this inertial navigation system can provide is to initiate a transmission to the provider system in the event the patient moves greater than a set distance, say 100 yards. The supplementation of a dead reckoning system beyond the DGPS or GPS provides for a second source for checking whether the patient has moved so the device should function through a GPS outage. Such a system could keep track of Alzheimer's patients with minimal supervision, for example.

Because of its current level of accuracy, wherever we can we would prefer to rely on the data from the modern DGPS systems for dynamic relative navigation.

Examples of systems currently taught include those described in U.S. Patent No. 5,689,431, and 5,680,140, and 5,583,517, all incorporated herein by this reference. Triangulation techniques of 5,784,339, and spread spectrum techniques of 5,583,517, both also incorporated by reference, may also be used if desired.

Fig. 10 illustrates the method by which the system of Fig 9 may be called upon to work. In step A, the real time clock is running, until at step B it is recognized that the real time clock is at the next time value of interest, that is the next day, hour or minute whenever the system needs to check on its location relative to the last good GPS or DGPS fixation reading. Alternatively, whenever the patient system is supposed to report in to the local medical provider system a real time clock setting can be associated with this step B. In any event, in step C, the processing capability of the system needs to be engaged to do whatever is required.

Step D has the system checking the high accuracy clock for comparison to the running real time clock in the patient local device or devices, such as the system 104 of Fig. 7, for example. If the time is accurate, then the device can simply process as normal, otherwise it needs to update the real time clock(s) it maintains so as to be able to communicate in its proper time slice within the local provider system.

In Step E, the system on the patient needs to check to see if the time from the properly updated real time clock is appropriate for it to send data, and if so, to activate the part of the system that communicates the data to the medical provider system. Otherwise if the time is not right, it can go back to Step A, and let the processor power stay off until the next value of interest is seen from the real time clock. (A description of power cycling to save battery life is found in U.S. Patent No. 5,592,173, incorporated by this reference, and a description of use of this in a vehicle location GPS system is in U.S. Patent No. 5,777,580, also incorporated by this reference).

For communication between an implanted device and an externally worn patient device, common telemetry techniques presently used by any pacemaker manufacturer may be employed, as well as less evident techniques such as is described in the Funke Body Bus of US Patent 4,987,897, or his acoustic bus, in 5,113,859, both incorporated herein by this reference.

Variations and modifications to the present invention may be possible given the above disclosure. Although the present invention is described in conjunction

with a microprocessor-based architecture, it will be understood that it could be implemented in other technology such as digital logic-based, custom integrated circuit (IC) architecture, if desired.

5 While there has been shown what are considered to be the preferred embodiments of the invention, it will be manifest that many changes and modifications may be made therein without departing from the essential spirit of the invention. It is intended, therefore, in the following claims to cover all such changes and modifications as may fall within the true scope of the invention.

CLAIMS

1. A system for communicating patient device information to and from a medical device implanted in an ambulatory patient and with a remote medical support network comprising:

an implanted device telemetry transceiver within the implanted medical device for communicating data and operating instructions to and from the medical device the implanted device telemetry transceiver having a tranceiving range extending outside the patient's body a distance sufficient to receive and transmit such telemetered communications; and

an external patient communications control device adapted to be located in relation to the patient within the device transceiving range including:

a system controller for facilitating communications with the implanted medical device;

an implant wireless interface including a control device telemetry transceiver for receiving and transmitting coded communications between the system controller and the implant device telemetry transceiver;

a global positioning system coupled to said system controller for providing positioning data identifying the global position of the patient to the system controller; and

communications means for communicating between the external communications control device and a remote medical support network.

2. The system of Claim 1 further comprising:

communications network interface means coupled to the system controller and the communications means for selectively enabling the communications means for transmitting the positioning data to the medical support network and for selectively receiving commands from the medical support network wherein said implantable wireless interface includes a real time clock and a system for updating said real time clock based on accurate time clock information in signals received from said global positioning system..

Claim 3. An emergency patient location system comprising:

a transceiver unit to be located in immediate proximity to a patient's body for communicating with a device implanted in the patient's body and with a telephone system outside the patient's body,

the transceiver unit comprising,

a GPS location system for receiving satellite location information from a set of earth orbiting satellites,

an IMD receiving telemetry circuit means for receiving telemetry from said implanted device,

a memory circuit for storing data relating to data received from said implanted device and from said earth orbital satellite,

telecommunications module for communication through wireless telephonic channels to said telephone system which may be associated with emergency response systems, and

circuit means for producing a representation of said received location information for presentation to said telecommunications module so that said telecommunications module can transmit said representation of said location information to location receiving means in said emergency response systems.

4. An emergency patient location system as set forth in claim 3 said transceiver unit further comprising;

DGPS receiver means for receiving DGPS signals from a base station, and wherein said circuit means for producing a representation of said received location information for presentation to said telecommunications module is configured to also provide DGPS information to said telecommunications module.

5. An emergency patient location system as set forth in claim 3 said transceiver unit further comprising;

dead reckoning circuit means for determining the relative location of said transceiver unit over time to any location at a fixed time during which an acceptable

fixed location of said transceiver unit is known, and wherein said circuit means for producing a representation of said received location information for presentation to said telecommunications module is configured to also provide a representation of said dead reckoning information to said telecommunications module.

6. An emergency patient location system as set forth in claim 5 said transceiver unit further comprising;

a distance traveled interpretive processor for receiving an output from said dead reckoning circuit and determining a distance traveled therefrom,

a trigger circuit for triggering the initiation of transmission to said telephone system by said telecommunications module when the distance traveled interpretive processor determines a distance traveled is greater than a predetermined trigger distance value.

7. An emergency patient location system as set forth in claim 3 further comprising a processor adapted for transmitting emergency information from said transceiver unit to an emergency E911 system.

8. A patient monitoring system comprising:

a transceiver unit to be located in immediate proximity to a patient's body for communicating with a device implanted in the patient's body and with a telephone system outside the patient's body, the transceiver unit comprising,

a GPS location system for receiving satellite transmitted information from a set of earth orbiting satellites,

an IMD receiving telemetry circuit means for receiving telemetry from said implanted device,

a memory circuit for storing data relating to data received from said implanted device and from said earth orbital satellite,

telecommunications module for communication through wireless telephonic channels to said telephone system,

real time clock circuit producing an output signal for a real time clock,
transmission initiation processor for generating an automatic transmission
over said telecommunications module through said wireless telephonic channels
containing information related through said implantable device to said transceiver
unit, said automatic transmission to occur at a set of periodically occurring fixed
times, and

real time clock circuit update processor for interpreting received satellite
transmitted information and providing an update for the real time clock circuit based
on said satellite transmitted information so that said transmission initiation processor
can operate within an extremely accurately clocked time slice.

9. A patient monitoring and emergency location system comprising;

a patient monitoring system as set forth in claim 8 and further comprising;

circuit means for producing a representation of said received satellite
information relating the location of said transceiver unit for presentation to said
telecommunications module so that said telecommunications module can transmit
said representation of said location information to location receiving means in an
emergency response system connected to said telephone system.

10. A patient monitoring and emergency location system as set forth in claim 9 said
transceiver unit further comprising;

DGPS receiver means for receiving DGPS signals from a base station, and
wherein said circuit means for producing a representation of said received location
information for presentation to said telecommunications module is configured to
also provide DGPS information to said telecommunications module.

11. A patient monitoring and emergency location system as set forth in claim 9 said
transceiver unit further comprising;

dead reckoning circuit means for determining the relative location of said
transceiver unit over time to any location at a fixed time during which an acceptable
fixed location of said transceiver unit is known, and wherein said circuit means for

producing a representation of said received location information for presentation to said telecommunications module is configured to also provide a representation of said dead reckoning information to said telecommunications module.

12. A patient monitoring and emergency location system as set forth in claim 9, said transceiver unit further comprising;

a distance traveled interpretive processor for receiving an output from said dead reckoning circuit and determining a distance traveled therefrom,

a trigger circuit for triggering the initiation of transmission to said telephone system by said telecommunications module when the distance traveled interpretive processor determines a distance traveled is greater than a predetermined trigger distance value

13. A patient monitoring and emergency location system as set forth in claim 9 further comprising a processor adapted for transmitting emergency information from said transceiver unit to an emergency E911 system.

14. Emergency response system for receiving location information from a transceiver unit in proximity to a patient with an implantable medical device in communication with said transceiver unit, said emergency response system comprising;

at least one mobile unit operational on an emergency basis for receiving location information from said transceiver unit and having a GPS system and a computer system therein, such that said mobile unit GPS system produces data related to a present location of said mobile unit and makes said data related to said present location of said mobile unit available to said computer system and said mobile unit computer system comprises processor means for processing said received location information from said transceiver unit and said data related to the present location of said mobile unit to produce an indication of the relative position of said transceiver unit to said mobile unit, and

a base station for receiving through a telephone system a current location representation from said transceiver unit along with status information related to an implantable device implanted within a patient associated with said transceiver unit.

15. Method for operation of a transceiver unit for wearing on a person having location means and means for communicating with an implant and with a telephone network comprising:

providing a telemetric communications pathway between an implanted medical device(IMD) and a patient word device(PWD) to facilitate the transfer from the IMD to the PWD of data relating to any of the following information types: a. Serial No. or other unique ID data, b. Patient Condition, c. Device status data, d. Device Sensor data, and/or e. coordinating data,

providing a telemetric communications pathway between an IMD and a PWD to facilitate the transfer from the PWD to the IMD of data relating to any of the following information types: a. Commands and /or b. Coordinating data,

providing a telemetric communications pathway between a node on a telephone network and said PWD and between a satellite GPS system and said PWD so as to facilitate the transfer of any of the following information types from said node and/or said satellite GPS system to said PWD: a. Command data and/or coordinating data, and

providing a telemetric communications pathway between a node on a telephone network and said PWD so as to facilitate the transfer of any of the following information types from said PWD to said node: PWD device data including any data received by the PWD from the IMD and/or any sensor data that may be developed and stored by the PWD and/or PWD status data and/or Dynamic Relative Reference data from a dead reckoning system associated with said PWD, and GPS and DGPS which may be stored by the PWD.

16. A method as set forth in claim 15 and further comprising

determining when said tranceiving unit has traveled a predetermined distance
and
upon said determination of having traveled said predetermined distance,
initiating a telephonic contact to a node on said telephone network.

5
17. A method as set forth in claim 15 and further comprising:
awaiting a determination of an emergency condition having occurred,
then initiating a telephonic contact to at least one node on said telephone
network when as emergency condition has arisen.

10
18. A method as set forth in claim 17 and further comprising:
sending coded data regarding the nature of the emergency to said at least one
node.

15
19. A method as set forth in claim 17 and further comprising:
sending location data regarding the location of the PWD to said at least one
node.

20
20. A method as set forth in claim 15 and further comprising:
awaiting a determination of an emergency condition having occurred,
then initiating a telephonic contact to an emergency system including a
system of the two systems, standard emergency system and/or to an E-911 system,
on said telephone network when as emergency condition has arisen.

25
21. A method as set forth in claim 20 and further comprising:
sending coded data regarding nature of the emergency to said emergency
system.

30
22. A method as set forth in claim 20 and further comprising:
sending location data regarding the location of the PWD to said emergency
system.

23. A method as set forth in claim 15 and further comprising
providing a real time clock system and a clock updating system for
correcting the value of real time clock information based on satellite signals to said
transceiver unit,

automatically using the corrected real time clock values to trigger an
automatic turn on a communication between said PWD and a node in a narrow time
slice, and

reporting to said node by said PWD some or all data facilitated for transfer
on that communications pathway.

24. A method as set forth in claim 23 further comprising,
receiving command data from said node by said PWD during an additional
narrow time slice.

25. A method as set forth in claim 24 further comprising,
transmitting a representation of said command data to said IMD from said
PWD.

26. A method as set forth in claim 25 further comprising;
receiving said representation of said command data in said IMD,
programming the IMD based on said representation of said command data.

27. A method of monitoring a patient having a transceiver associated therewith and
an implanted medical device in communication with said transceiver comprising;
monitoring GPS and DGPS location data by said transceiver,
interpreting said location data by said transceiver and
if said location data interpreted by said transceiver indicates the patient
transceiver is outside a predetermined area,
initiating a telephone call by said transceiver to a telephone node on a
telephone network, indicating the present location of said transceiver.

28. A method of monitoring a patient having a transceiver associated therewith and an implanted medical device in communication with said transceiver comprising;

5 monitoring the implanted medical device for either a lack of signal over a predetermined period of time or for an alarm signal generated by said implanted medical device and

if either said alarm signal is received or if said lack of signal exists over said predetermined period of time,

10 automatically initiating an emergency telephone call by said transceiver to a node on a telephone network indicating an alarm condition to said node.

29. A method of operating an emergency patient location system comprising,

15 providing said system with patients having implanted medical devices and transceiver units for monitoring communications from said implanted medical devices,

providing said transceiver units with means to receive GPS data and to store said GPS data,

20 providing said transceiver units with telecommunications equipment, awaiting the development of emergency conditions to be reported by said transceiver units to said system across telephonic communications pathways,

dispatching emergency mobile units having receiver means tuned to receive signals from said transceiver unit reporting said emergency condition

reporting from said transceiver unit location information,

receiving said location information in said emergency mobile unit and

25 employing said location information by said emergency mobile unit to locate the patient having the reported emergency.

30. Method as set forth in claim 29 further comprising continuously transmitting a signal by said transceiver unit after reporting said emergency condition and wherein said employing step includes triangulation on a signal transmitted by said transceiver unit after said transceiver unit initially reports said emergency condition

31. Method as set forth in claim 29 wherein said location information transmitted by said transceiver unit includes DGPS information.

- 5 32. Method as set forth in claim 29, wherein said location information transmitted by said transceiver unit includes dead reckoning information.

ABSTRACT OF THE DISCLOSURE

A system for communicating with a medical device implanted in an ambulatory patient and for locating the patient in order to selectively monitor device function, alter device operating parameters and modes and provide emergency assistance to and communications with a patient. The implanted device includes a telemetry transceiver for communicating data and operating instructions between the implanted device and an external patient communications control device that is either worn by or located in proximity to the patient within the implanted device tranceiving range. The control device preferably includes a communication link with a remote medical support network, a global positioning satellite receiver for receiving positioning data identifying the global position of the control device, and a patient activated link for permitting patient initiated personal communication with the medical support network. A system controller in the control device controls data and voice communications for selectively transmitting patient initiated personal communications and global positioning data to the medical support network, for initiating telemetry out of data and operating commands from the implanted device and transmission of the same to the medical support network, and for receiving and initiating re-programming of the implanted device operating modes and parameters in response to instructions received from the medical support network. The communications link between the medical support network and the patient communications control device may comprise a world wide satellite network, hard-wired telephone network, a cellular telephone network or other personal communications system. Methods and apparatus are also described that enhance the ability of the medical system to find patients and to get reports on patient and medical device status, and even update medical device programming using such facilities, and others described in detail within.

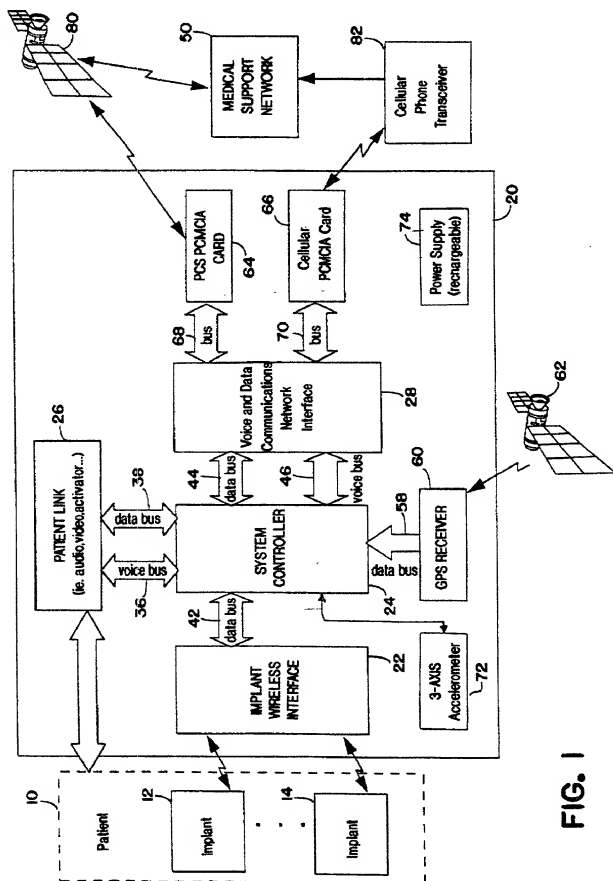
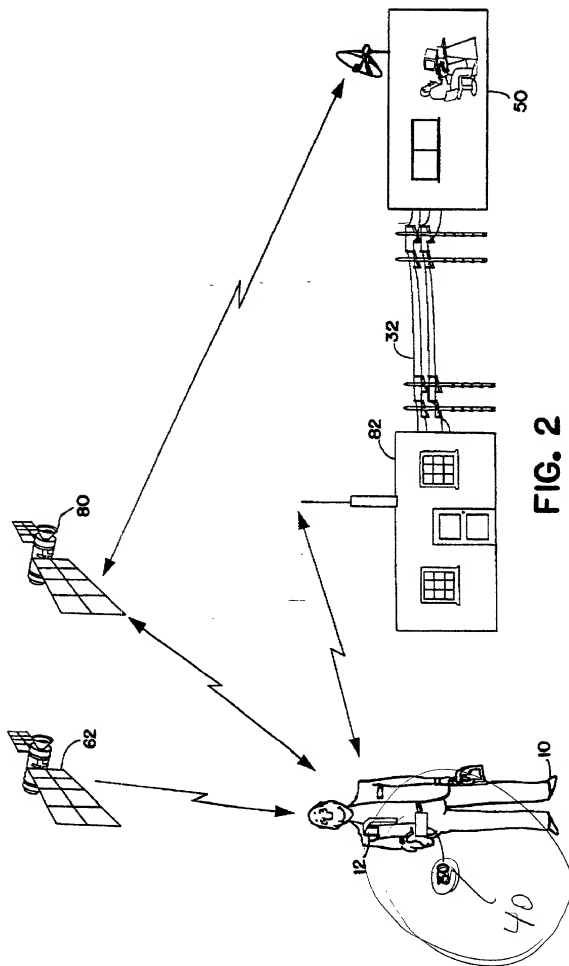


FIG. 1



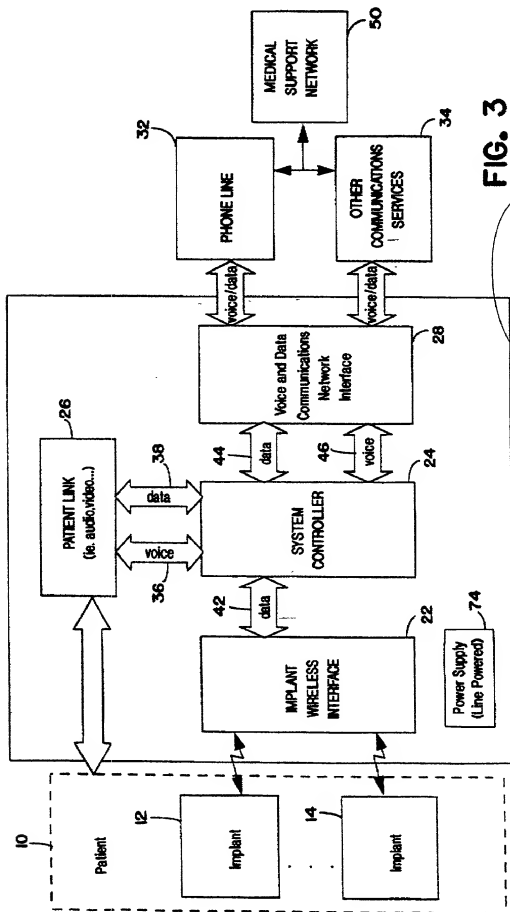


FIG. 3

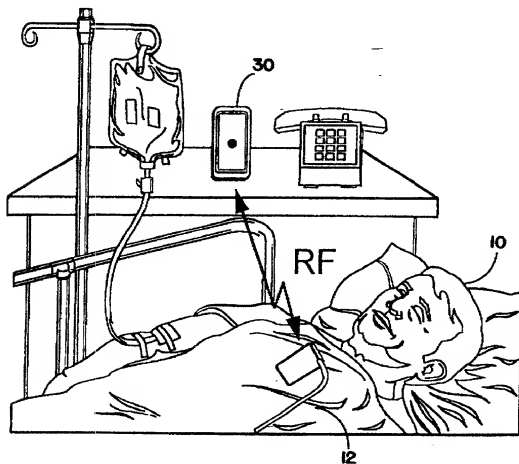


FIG. 4

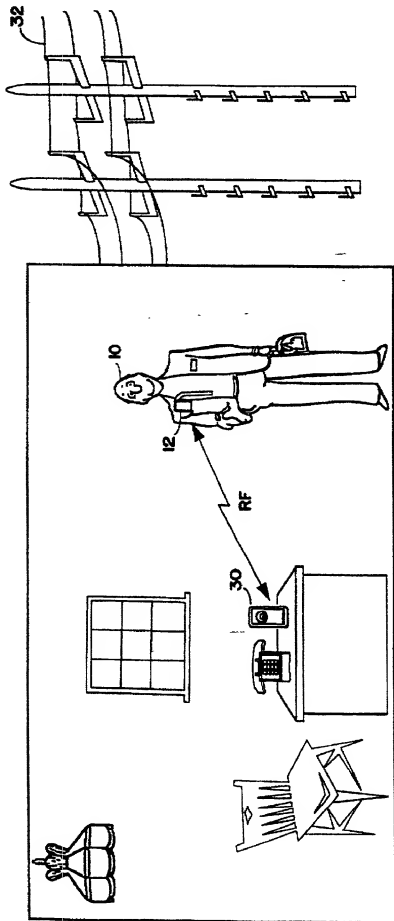


FIG. 5

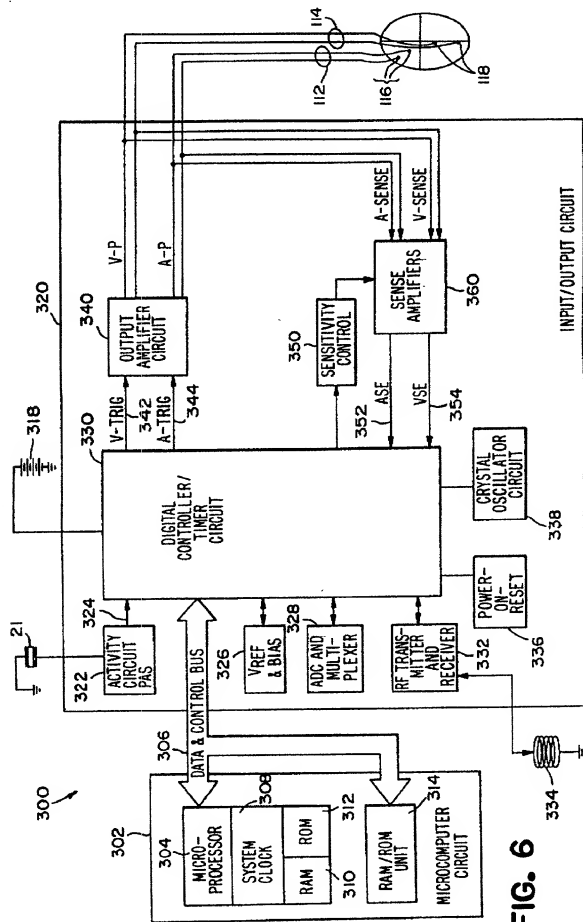


FIG. 6

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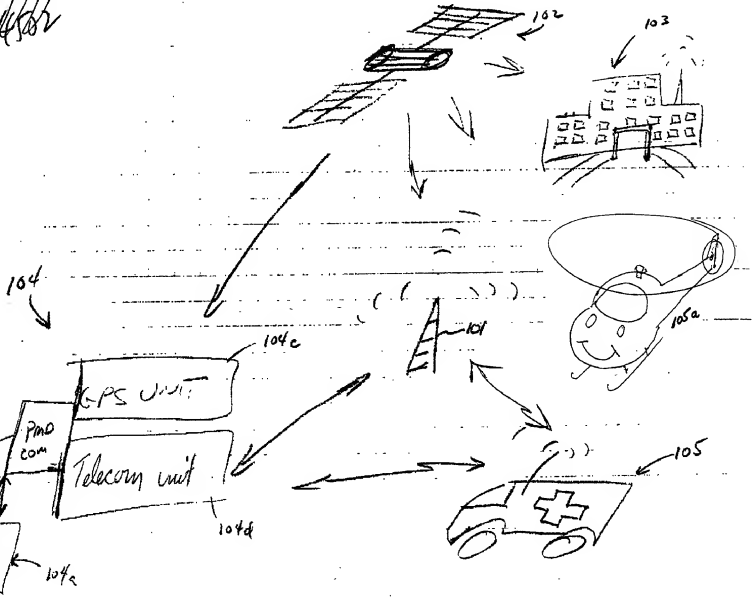


Fig. 7

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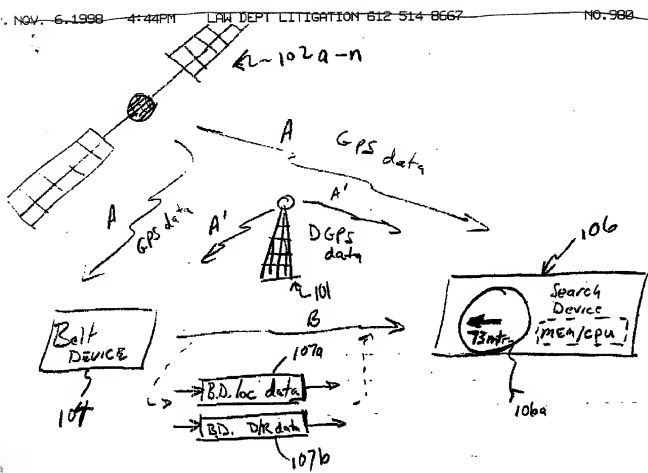


Fig. 8.

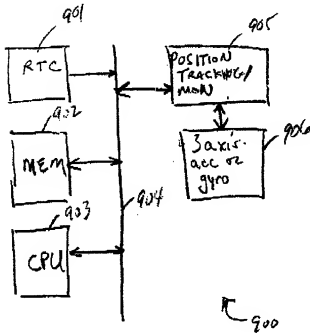


Fig. 9.

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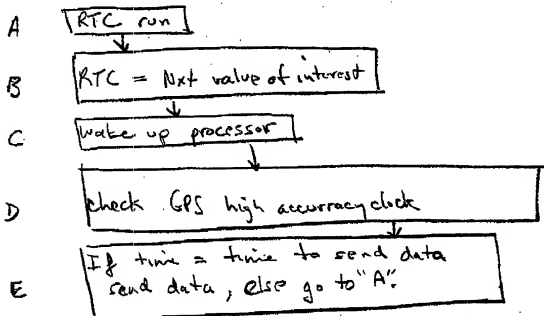


Fig. 10

P-3576.07 CIP

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **WORLD WIDE PATIENT LOCATION AND DATA TELEMETRY SYSTEM FOR IMPLANTABLE MEDICAL DEVICES**.

The specification of which

a. is attached hereto

b. _____ was filed on _____ as application serial no. _____ and was amended on (if applicable) (in the case of a PCT-filed application) described and claimed in international no. _____ filed _____ and as amended on _____ (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).¹

I hereby claim foreign priority benefits under Title 35, United States Code, §119/365 of any foreign application(s) for patent of inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

a. ☒ no such applications have been filed.

b. _____ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC §119

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

ALL FOREIGN APPLICATIONS, IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

I hereby claim the benefit under Title 35, United States Code, §120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

¹ § 1.56 Duty of disclosure; fraud, striking or rejection of applications.

(a) A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.

U. S. APPLICATION NUMBER	DATE OF FILING	STATUS (patented, pending, abandoned)
08/494,218	June 23, 1995	Issued
09/045275	March 20, 1998	pending

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Harold R. Patton
Reed A. Duthler
Daniel W. Latham
Michael B. Atlasi
Peter Forrest

Reg. No. 22,157
Reg. No. 30,626
Reg. No. 30,401
Reg. No. 30,606
Reg. No. 33,235

Dianne M.F. Plunkett
Michael J. Jaro
Curtis D. Kinghorn
Thomas F. Woods

Reg. No. 35,649
Reg. No. 34,472
Reg. No. 33,926
Reg. No. 36,726

Please direct all correspondence in this case to:

Michael B. Atlasi
Medtronic, Inc.
7000 Central Avenue N.E.
Minneapolis, Minnesota 55432
Telephone No. (612) 514-3066

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2	Full Name of Inventor	FIRST NAME David	MIDDLE INITIAL L.	LAST NAME Thompson
0	RESIDENCE & CITIZENSHIP	CITY Fridley	STATE OR FOREIGN COUNTRY Minnesota	COUNTRY OF CITIZENSHIP US
1	POST OFFICE ADDRESS	POST OFFICE ADDRESS 1660 Onondaga Street	CITY Fridley	STATE/ZIP/COUNTRY Minnesota 55432 US
SIGNATURE OF INVENTOR 201				Date 11/24/98
2	Full Name of Inventor	FIRST NAME	MIDDLE INITIAL	LAST NAME
0	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
2	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE/ZIP/COUNTRY
SIGNATURE OF INVENTOR 202				Date
2	Full Name of Inventor	FIRST NAME	MIDDLE INITIAL	LAST NAME
0	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
3	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE/ZIP/COUNTRY
SIGNATURE OF INVENTOR 203				Date
2	Full Name of Inventor	FIRST NAME	MIDDLE INITIAL	LAST NAME
0	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
4	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE/ZIP/COUNTRY
SIGNATURE OF INVENTOR 204				Date